Remarks

This Amendment is in response to the Office Action dated **September 11, 2008.**

Election/Restriction

Applicants previously elected group I, claims 1-30 and 53-56, drawn to a medical device in response to the restriction requirement dated April 8, 2008. Claims 31-52 have been canceled without prejudice. Applicants reserve the right to prosecute these claims in a divisional application.

Rejections

35 U.S.C. §112

Claims 15, 17 and 27 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is asserted in the Office Action that:

> Claim 15 refers to a "freestanding" multilayer region. Is applicant claiming a coating without the medical device? Clarification is requested as this would constitute an improper further limiting of the invention from claim 1.
>
> Similarly, claim 17 refers to a temporary structure which is not implanted. As above, clarification is requested and for the same reasons.
>
> Clarification is requested as to what constitutes a "residue from a removable substrate adjacent to said multilayer region". This could not be found in the specification.

Applicants traverse the rejection with respect to claim 15.

Claim 1 is directed to an embodiment of a medical device including a multilayer region, the multilayer region comprising a charged nanoparticle layer comprising charged

nanoparticles and a plurality of charged polyelectroyte layers comprising charged polyelectrolyte. species, wherein said medical device is configured for implantation or insertion into a subject.

Claim 15 is directed to an embodiment wherein at least a portion of the multilayer region is "freestanding".

As is clear from the present specification, the substrate over which the multilayer region is formed, may form a permanent part of the medical device, or it may be a template over which the multilayer region is formed. See paragraphs [0058] to [0061], for example.

Claim 15 is does therefore not improperly limit claim 1.

Furthermore, a new independent claim 57 incorporating both the limitations of claims 1 and 15 has been added. New claim 57 is seen as being patentably distinct over WO 01/78906.

Likewise, claim 17 does refer to an article that is implanted. As is disclosed in the specification, the multilayer region can be formed over a removable substrate, leaving the multilayer region being freestanding, and forming at least a portion of the medical device. See paragraphs [0058] to [0061], for example.

Claim 27 is directed to an embodiment of a medical device wherein a removable substrate is employed to form the multilayer region and a residue from a removable substrate is left adjacent to the multilayer region. Applicants submit that the term "residue" is self-explanatory to those of ordinary skill in the art. Clearly, in the case wherein a removable substrate is employed to form the multilayer region, some of the removable substrate may be left if so desired. For example, in the case of meltable, dissolvable, or otherwise removable substrates, a portion, i.e. residue, of the removable substrate can be left in place adjacent the multilayer region if desired.

Applicants respectfully request withdrawal of the rejection of claims 15, 17 and 27 under 35 U.S.C. §112, first paragraph.

35 U.S.C. §102(b)

Claims 1-9, 13-24 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 01/78906 (Spillman).

Claim 1 has been amended to recite that the multilayer region of the medical device includes a charged nanoparticle layer comprising charged nanoparticles, a plurality of charged polyelectroyte layers comprising charged polyelectrolyte species, and at least one charged therapeutic agent, and said medical device is configured for implantation or insertion within a subject.

Claim 10 has been canceled accordingly.

Claim 13 has been amended for purposes of antecedent basis.

Claim 30 has been amended to depend from claim 1 instead of canceled claim 10.

Applicants submit that Spillman fails to disclose or suggest a multilayer region of the type recited in claim1 that includes a charged therapeutic agent.

"Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Finisar Corp. v. DirecTV Group Inc.*, 86 USPQ2D 1609, 1618 (Fed. Cir. 2008) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 [220 USPQ 193] (Fed. Cir. 1983) (citing *Soundscriber Corp. v. United States*, 360 F.2d 954, 960 (Ct. Cl. 1966) (emphasis added))). See also *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 as amended is not anticipated by Spillman.

Claims 2-9 and 13-24 depend from claim 1 and are not anticipated by Spillman for at least the reasons that claim 1 is not anticipated by Spillman.

Applicants respectfully request withdrawal of this rejection.

Allowable Subject Matter

Claims 10-12 and 25-30 are objected to as dependent upon a rejected base claim.

Claims 25, 27 and 28 have been rewritten in independent format.

Claims 10-12 and 30 depend from amended claim 1.

Claim 26 depends from amended claim 25.

Claim 29 depends from amended claim 30.

CONCLUSION

Claims 1-30 and 53-57 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Claims 53-56 were not acted upon but depend from amended claim 1. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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By: /Lisa Ryan-Lindquist/
Lisa R. Lindquist
Registration No.: 43071

6640 Shady Oak Dr., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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